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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,382	12/29/2004	Alain Sanson	263859US0X PCT	7625

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
10/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/518,382	SANSON ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6-6-08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,21-23,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4 and 27* is/are allowed.

6)☒ Claim(s) *1,2,5-11,21-23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-11, 21-23, 26 and 27 in the reply filed on July 02, 2007 is acknowledged.

2. The amendment filed, 4-24-08, is acknowledged. Claims 1, 2, 4-11, 21-23, 26-27 were amended, claims 28-29 were added. Claims 1, 2, 4-11, 21-23, 26-27 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 5-11, 21-23, 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of

> ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative

species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to peptides labeled with fluorine-18 in that the peptide comprises formula (I). Formula (I) discloses a sequence with 12 amino acids specifically disclosed and 62 amino acids that can be selected form a Markush Group. Variable J is present in 47 different amino acid position. The claims state that variable J can be any amino acid but 50% of them have to be selected from Arg, Asn, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, and Tyr. Assuming that 100% of the J are selected from the above Markush Group, there are 5.46×10^{21} different possible sequence incompassed by the claims ($47^{13} = 5.46 \times 10^{21}$). This total does not account for the possibility of variable U, B and Z nor do they account for "derivatives" of amino acids permitted for variable J. Taking into account these variable and the fact that only 50% of the J variables have be selected form 13 specific residues, the total number of peptides encompassed by the claim 1 exceed 5.46×10^{21}. While the specification does provide specific sequences these are limited to 14 specific sequences. These peptides disclosed share some level of homology amongst one another.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible peptides encompassed by the claims. The sequence variation with

the 5.46 x 10^{21} different sequences are limitless. "Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus." The disclosure of 14 specific sequences form a genus exceeding greater than 5.46 x 10^{21} peptides does not adequately reflect the variance of the genus. The disclosure does not identify the derivatives of amino acids encompassed by the claimed invention. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Response to Arguments

Applicants argue that the claims as amended define 29 of the 75 amino acids within the sequence. Furthermore, positions 59 and 65 must chosen from Glu, Asp, Lys, Arg. Nearly 50% of the amino acid sequence is identifiable and these position are involved in affinity of the peptide for phospholipids, toxicity, thermodynamic stability and reversibility in their folding process.

Applicants arguments have been fully considered but have not been found persuasive.

Firstly, while Applicants assert that the position are involved in affinity of the peptide for phospholipids, toxicity, thermodynamic stability and reversibility in their folding process, the specification does not convey to one of ordinary skill in the art, with reasonable clarity, that only those 29 amino acids residues are necessary for its function. Certainly there is empirical evidence to

the contrary since the specification and claims require that at least 50% of the J variable be selected from polar residues. Had these amino acids been unimportant, the would be allowed to be anything. Rather, the specification calls for at least 50% to be specific polar residues. The J amino acids are on the surface and are exposed to the solvent. Thus, these must function in providing some stability in solution. One cannot conclude from the specification that the 29 amino acids present would allow one to conclude of a known or disclosed correlation between function and structure. Furthermore, while the specification does provide specific sequences these are limited to 14 specific sequences. These peptides disclosed share some level of homology amongst one another.

Rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

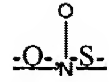
4. Claims 1-2, 5-11, 21-23, 26-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the label can be bound "directly or indirectly" with the peptide. While direct conjugation is readily understood, it unclear as to the precise definition of compound of (CI) indirectly bound to the peptide. That is, what types of associations are permitted to render the binding indirect? The specification does not describe nor exemplify indirect binding.

In claim 1, the claims still recites for variable m and n that the integer is from 0 to 10, such as 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10. The recitation of such as 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 seems redundant since 0 to 10 can only include such as 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10. Note that this recitation is present for the β radical.

In claim 3, the as to the recitation of Ex. While the claim states that Ex is example, it is unclear if the variables of U and B are required to those listed in the table or are mere examples and the claim does not further limit the variables recited in the base claim 1.

In claim 1, for variables V and W, the amdendment as written is unclear. It is unclear what



molecular species the amendment is attempting to state with .

Variable Z7 is now undefined in the claims.

Response to Arguments

Applicants argue that the claims have been amended to recite that the variable U and B are selected according to one of examples a) to j) in the table.

However, the claims is still indefinite. It is unclear any of the U's can be any amino acids defined for a specific U. More specifically, example a refers to U8 as Val, U11 as leu etc.. Thus, if "example a)" is selected, must variables U8, 15, 25, 29, 37, 44, 52, 56, 60 and 72 be selected from only those amino acids recited in example a or can some U variable have different substitutions as recited in say example k).

Furhtermore, Applicants did not address "indirect" labeling. While direct conjugation is readily understood, it unclear as to the precise definition of compound of (CI) indirectly bound to

the peptide. That is, what types of associations are permitted to render the binding indirect? The specification does not describe nor exemplify indirect binding.

5. Claims 4 and 29 are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Note that the inclusion of certain claims in the 112 rejections were necessitated by Applicants amendments.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654